

Summary Public Assessment Report

Bisoprolol Bausch Health (bisoprolol fumarate)

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Bisoprolol Bausch Health
bisoprolol fumarate

Film-coated tablet, 1,25 mg, 3,75 mg, 7,5 mg

This is a summary of the public assessment report (PAR) for Bisoprolol Bausch Health. It explains how Bisoprolol Bausch Health was assessed and its authorisation recommended as well as its conditions of use. It is not intended to provide practical advice on how to use Bisoprolol Bausch Health.

For practical information about using Bisoprolol Bausch Health, patients should read the package leaflet or contact their doctor or pharmacist.

What is Bisoprolol Bausch Health and what is it used for?

Bisoprolol Bausch Health is a 'generic medicine'. This means that it is similar to a 'reference medicine' already authorised in the European Union (EU) called Emconcor CHF.

Bisoprolol Bausch Health is used to treat stable chronic heart failure. It is used in combination with other medicines suitable for this condition (such as ACE-inhibitors, diuretics, and heart glycosides).

How does Bisoprolol Bausch Health work?

Bisoprolol Bausch Health belongs to a group of medicines called beta-blockers. These medicines work by affecting the body's response to some nerve impulses, especially in the heart. As a result, bisoprolol slows down the heart rate and makes the heart more efficient at pumping blood around the body. Heart failure occurs when the heart muscle is weak and unable to pump enough blood to supply the body's needs.

How is Bisoprolol Bausch Health used?

The pharmaceutical form of Bisoprolol Bausch Health is a film-coated tablet for oral use.

Please read section 3 of the package leaflet for detailed information on dosing recommendations, the route of administration, and the duration of treatment.

The medicine can only be obtained with a prescription in Sweden.

What benefits of Bisoprolol Bausch Health have been shown in studies?

Because Bisoprolol Bausch Health is a generic medicine, studies in patients have been limited to tests to determine that it is bioequivalent to the reference medicine, Emconcor CHF.

Two medicines are bioequivalent when they produce the same levels of the active substance in the body.

What are the possible side effects from Bisoprolol Bausch Health?

Because Bisoprolol Bausch Health is a generic medicine, its benefits and possible side effects are taken as being the same as the reference medicine.

For the full list of side effects, see section 4 of the package leaflet.

For the full list of restrictions, see the package leaflet.

Why is Bisoprolol Bausch Health approved?

It was concluded that, in accordance with EU requirements, Bisoprolol Bausch Health has been shown to have comparable quality and is considered to be bioequivalent to the reference medicine Emconcor CHF. Therefore, the Swedish Medical Products Agency decided that, as for Emconcor CHF, the benefits are greater than its risks and recommended that it can be approved for use.

What measures are being taken to ensure the safe and effective use of Bisoprolol Bausch Health?

A risk management plan has been developed to ensure that Bisoprolol Bausch Health is used as safely as possible. Based on this plan, safety information has been included in the summary of product characteristics and the package leaflet for Bisoprolol Bausch Health, including the appropriate precautions to be followed by healthcare professionals and patients.

Known side effects are continuously monitored. Furthermore, new safety signals reported by patients/healthcare professionals will be monitored/reviewed continuously as well.

Other information about Bisoprolol Bausch Health

The full PAR for Bisoprolol Bausch Health can be found on the following website: <http://mri.medagencies.org/Human/>. For more information about treatment with Bisoprolol Bausch Health, please read the package leaflet or contact your doctor or pharmacist.

This summary was last updated in 2022-06.